MAY 02 2014
K133934

Links Medical Products Inc.

510(k) SUMMARY

Submitted by:

Owner's Name:	Links Medical Products, Inc.
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Date Prepared: April 1, 2014

Trade Name: MANUKA FOAM HC

Common Name: Wound Dressing

Classification Name: Dressing, Wound, Drug

Device Class: Unclassified

Product Code: FRO

Predicate Devices: MANUKA IG Wound Dressing (Links Medical Products, Inc.), BioAquaCare (BioArtificial Gel Technologies)

Predicate 510(k) #: K120976 (MANUKA IG), K072068 (BioAquaCare)

Device Description: MANUKA FOAM HC wound dressings are sterile, single use wound care dressings that help maintain a moist wound environment. The primary device consists of 100% *Leptospermum scoparium* honey from New Zealand impregnated into an absorbent foam-fiber hybrid material. One version of the product includes a polyurethane border

with a silicone adhesive. Another version of the product includes a polyurethane border with an acrylic adhesive.

Intended Use: MANUKA FOAM HC wound dressings are sterile, single-use wound care dressings for use in moist wound management of:

- Leg Ulcers
- Pressure Ulcers
- 1st and 2nd Degree Burns
- Diabetic Foot Ulcers
- Surgical Wounds
- Trauma Wounds

A moist wound environment allows autolytic debridement of necrotic tissue.

Technology Comparison: The technical characteristics of MANUKA FOAM HC are substantially equivalent to the predicate devices: Manuka IG and BioAquaCare. MANUKA FOAM HC and its predicate devices maintain a moist wound environment that promotes autolytic debridement conducive to wound healing. Like MANUKA FOAM HC, Manuka IG maintains a moist wound environment by using 100% *leptospermun scoparium* honey as the primary ingredient, and uses an absorbent secondary dressing to manage excess wound exudate. BioAquaCare utilizes a hydrogel (95% water) to maintain a moist wound environment. MANUKA FOAM HC and its predicates are provided as single-use devices in individually sterilized packaging. Despite minor differences in materials, the devices are similar in function and intended use.

Nonclinical Testing: Standard biocompatibility tests were performed on the MANUKA FOAM HC wound dressings, in accordance with ISO 10993-1 (Biological Evaluation of Medical Devices) and the FDA Biocompatibility Matrix, including cytotoxicity, primary skin irritation, and skin sensitization. In addition, a wound healing study was conducted to assess the impact of repeated application of MANUKA FOAM HC wound to full-thickness dermal wounds in swine. The test articles did not impair healing and were determined to be as safe and effective as the predicate devices. All tests were

performed by North American Science Associates (NAMSA). Additional testing included sterilization validation, shelf-life under accelerated and real-time conditions, and packaging validation. The MANUKA FOAM HC wound dressings met the acceptance criteria for all tests conducted.

Conclusion of Comparison: MANUKA FOAM HC and its predicate devices were demonstrated to be biocompatible and met performance requirements for sterility, shelf life, and packaging. Based upon the technological characteristics and nonclinical performance data, MANUKA FOAM HC wound dressings have been determined to be substantially equivalent and as safe and effective as its predicate devices (Manuka IG and BioAquaCare).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 2, 2014

Links Medical Products Incorporated
Mr. James Smith
Consultant
29442 Pointe Royale
Laguna Hills, California 92677

Re: K133934
Trade/Device Name: MANUKA FOAM HC
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 31, 2014
Received: February 6, 2014

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
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Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K133934

Device Name: MANUKA FOAM HC

Indications for Use:

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A moist wound environment allows autolytic debridement of necrotic tissue.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use: ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter L. Hudson -S